

WE CLAIM:

1. A mold for the manufacture of an endovascular graft or section

5 thereof which has at least one inflatable channel or cuff, comprising:

a plurality of mold body portions configured to mate with at least one of the other mold body portions to produce an assembled mold having a main cavity portion with an inside surface contour that matches an outside surface contour of the endovascular graft section with the at least one inflatable channel or cuff in an expanded state.

2. The mold of claim 1 further comprising at least one channel cavity that has an inside surface contour that corresponds to an outside surface contour of the at least one inflatable channel in an expanded state.

15 3. The mold of claim 1 further comprising at least one cuff cavity that has an inside surface contour that corresponds to an outside surface contour of the at least one inflatable cuff in an expanded state.

4. The mold of claim 1 further comprising at least one longitudinal channel cavity that has an inside surface contour that corresponds to an 20 outside surface contour of an inflatable longitudinal channel of the graft section in an expanded state.

5. The mold of claim 1 further comprising at least one helical channel cavity that has an inside surface contour that corresponds to an

outside surface contour of an inflatable helical channel of the graft section in an expanded state.

6. The mold of claim 1 wherein the mold body portions comprise sintered metal.

5 7. The mold of claim 1 further comprising at least one exhaust channel in fluid communication with the main cavity portion of the mold and a position outside the mold.

8. The mold of claim 7 wherein the exhaust channel is disposed on a contact surface of a mold body portion.

9. The mold of claim 1 wherein the mold body portions comprise aluminum.

10. The mold of claim 1 wherein the main cavity portion has a length of about 50 to about 300 mm.

11. The mold of claim 1 wherein the main cavity portion has an inner 15 transverse dimension of about 4 to about 50 mm.

12. The mold of claim 2 comprising a plurality of channel cavities configured as circumferential channel cavities and at least one longitudinal channel cavity in fluid communication with the circumferential channel cavities.

13. The mold of claim 2 comprising a plurality of channel cavities 20 configured as circumferential channel cavities and at least one helical channel cavity in fluid communication with the circumferential channel cavities.

14. The mold of claim 1 further comprising a first tapered portion disposed at a first end of the main cavity portion and a second tapered portion

disposed at a second end of the main cavity portion, wherein the first and second tapered portions taper to an increased transverse dimension toward respective first and second ends of the mold.

15. A mold for manufacture of an endovascular graft or section
5 thereof which has at least one inflatable channel or cuff, comprising:

- a first mold body portion having a main cavity portion with an inside surface contour that is configured to correspond to an outside surface contour of the graft section with the at least one inflatable channel or cuff in an expanded state; and
- a second mold body portion configured to mate with the first mold body portion having a main cavity portion with an inside surface contour that is configured to correspond to an outside surface contour of the graft section with the at least one inflatable channel or cuff in an expanded state.

15 16. The mold of claim 15 further comprising at least one channel cavity that has an inside surface contour that corresponds to an outside surface contour of the at least one inflatable channel in an expanded state.

20 17. The mold of claim 15 further comprising at least one cuff cavity that has an inside surface contour that corresponds to an outside surface contour of the at least one inflatable cuff in an expanded state.

18. The mold of claim 15 further comprising at least one longitudinal channel cavity that extends longitudinally along an inside surface contour of a main cavity portion of the mold and that has an inside surface contour that

corresponds to an outside surface contour of an inflatable longitudinal channel of the graft section in an expanded state.

19. The mold of claim 15 further comprising at least one helical channel cavity within the main cavity portion of the mold that has an inside 5 surface contour that corresponds to an outside surface contour of an inflatable helical channel of the graft section in an expanded state.

20. The mold of claim 15 wherein the mold body portions comprise a sintered metal.

21. The mold of claim 15 further comprising at least one exhaust channel in fluid communication with the main cavity portion and a position 10 outside the mold.

22. The mold of claim 15 wherein the exhaust channel is disposed on a contact surface of the mold body portion.

23. The mold of claim 15 wherein the mold body portions comprise 15 aluminum.

24. The mold of claim 15 wherein the main cavity portion has a length of about 50 to about 300 mm.

25. The mold of claim 15 wherein the main cavity portion has an inner transverse dimension of about 5 to about 50 mm.

20 26. The mold of claim 16 comprising a plurality of channel cavities configured as circumferential channel cavities and at least one longitudinal channel cavity in fluid communication with the circumferential channel cavities.

27. The mold of claim 16 comprising a plurality of channel cavities configured as circumferential channel cavities and at least one helical channel cavity in fluid communication with the circumferential channel cavities.

28. The mold of claim 15 further comprising a first tapered portion 5 disposed at a first end of the main cavity portion and a second tapered portion disposed at a second end of the main cavity portion.

29. A pressure line for use in the manufacture of an endovascular graft or section thereof, comprising:

an elongate conduit having an input end, an output end and a permeable section that has a permeability gradient which increases with distance from the input end.

30. The pressure line of claim 29 wherein the permeability of the pressure line increases about 5 to about 20 percent per centimeter in a direction from the input end to the output end along the permeable section.

15 31. The pressure line of claim 29 wherein the permeability gradient results from a plurality of outlet orifices disposed in the elongate conduit which increase in diameter with an increase in distance from the input end.

20 32. The pressure line of claim 31 wherein the outlet orifices are spaced longitudinally from each other so as to match a longitudinal spacing of a plurality of circumferential inflatable channels of the endovascular graft.

33. The pressure line of claim 29 further comprising an input port, a proximal section and a distal section wherein the proximal section comprises stainless steel and the distal section comprises a polymer.

34. The pressure line of claim 33 wherein the distal section has an outer transverse dimension of about 0.01 to about 0.1 inch.

35. The pressure line of claim 29 wherein the length of the pressure line is about 2 to about 12 inches.

5 36. The pressure line of claim 29 wherein a transverse cross section of at least a portion of the proximal section is D-shaped.

37. A mandrel for shape forming an endovascular graft, or section thereof, comprising:

10 a middle section;
a first end section with at least a portion that has a larger outer transverse dimension than an outer transverse dimension of the middle section and which is removably secured to a first end of the middle section; and

15 a second end section disposed at a second end of the middle section with at least a portion that has a larger outer transverse dimension than an outer transverse dimension of the middle section.

38. The mandrel of claim 37 wherein the second end section is removeably secured to a second end of the middle section.

20 39. The mandrel of claim 38 wherein the first end section and second end section are removably secured to the middle section by threaded portions.

40. The mandrel of claim 37 wherein the middle section is about 50 to about 150 mm in length.

41. The mandrel of claim 37 wherein the outer transverse dimension of the middle section is about 5 to about 50 mm.

42. The mandrel of claim 37 wherein the outer transverse dimension of the middle section is about 15 to about 30 mm.

5 43. The mandrel of claim 37 wherein the outer transverse dimension of the first end section is about 15 to about 40 mm.

44. The mandrel of claim 37 wherein the middle section further comprises a pressure line recess that includes a longitudinal groove formed in an outer surface of the middle section and which is configured to accept a pressure line.

45. The mandrel of claim 39 wherein the first end section, second end section and middle section comprise stainless steel.

46. The mandrel of claim 37 wherein the first end section, second end section and middle section are substantially circular or elliptical in transverse 15 cross section.

47. The mandrel of claim 44 wherein the transverse cross section of the longitudinal channel has a radius of curvature of about 0.005 to about 0.05 inch.

20 48. The mandrel of claim 46 wherein a longitudinal axis of the first end section, second end section and middle section are substantially coaxial.

49. An assembly for manufacture of an endovascular graft or section thereof which has at least one inflatable cuff or channel on the graft section, comprising:

15 a) a mandrel comprising an elongate body having an outer surface contour configured to support an inside surface of the endovascular graft;

5 b) the graft section having at least one inflatable cuff or channel disposed about at least a portion of the mandrel;

15 c) a pressure line comprising an elongate conduit having an input end, an output end and a permeability gradient which increases with distance from the input end and which is in fluid communication with an inflatable cuff or channel of a main body portion of the endovascular graft;

20 d) a mold at least partially disposed about the graft section, the pressure line and the mandrel, comprising a plurality of mold body portions configured to mate together to produce an assembled mold having a main cavity portion with an inside surface contour that matches an outside surface contour of the graft section with the at least one inflatable cuff or channel in an expanded state and configured to radially constrain an outer layer or layers of the at least one inflatable cuff or channel during expansion of the cuff or channel.

20 50. The assembly of claim 49 wherein the pressure line is at least partially disposed within an inflatable cuff or channel of the graft.

51. The assembly of claim 50 wherein the permeability gradient of the pressure line results from a plurality of orifices disposed in the elongate

conduit which increase in diameter as distance from the input end of pressure line increases.

52. The assembly of claim 51 wherein the plurality of orifices are substantially aligned with circumferential channel cavities of the mold.

5 53. The assembly of claim 49 wherein the mandrel comprises a middle section; a first end section with at least a portion that has a larger outer transverse dimension than an outer transverse dimension of the middle section and which is removably secured to a first end of the middle section; and

a second end section disposed at a second end of the middle section with at least a portion that has a larger outer transverse dimension than an outer transverse dimension of the middle section.

54. The assembly of claim 53 wherein the mandrel further comprises 15 a pressure line recess that includes a longitudinal groove formed in an outer surface of the mandrel.

55. The assembly of claim 51 wherein the orifices of the pressure line are substantially aligned with inflatable channels of the main body portion.

56. A method of forming at least one inflatable channel or cuff of an 20 endovascular graft or section thereof comprising:

a) providing a graft section with at least one inflatable channel or cuff formed between layers of graft material of the graft section in an unexpanded state;

b) providing a mold comprising a main cavity portion having an inside surface contour that corresponds to an outside surface contour of the graft section with the at least one inflatable channel or cuff in an expanded state;

5 c) positioning the graft section in the main cavity portion of the mold with the at least one inflatable channel or cuff of the graft section in an unexpanded state and positioned to expand into corresponding channel or cuff cavity portions of the main cavity portion;

d) injecting pressurized fluid into the at least one inflatable channel or cuff to expand the at least one inflatable channel or cuff;

e) fixing the graft material of the at least one inflatable channel or cuff with the at least one inflatable channel or cuff in an expanded state.

57. The method of claim 56 further comprising positioning a pressure

15 line comprising an elongate conduit having a permeable section with a permeability gradient in fluid communication with at least one inflatable channel or cuff of the graft section and injecting the pressurized fluid into the at least one inflatable channel or cuff through the permeable section of the pressure line.

20 58. The method of claim 57 wherein the pressure line is positioned within a temporary longitudinal inflation channel of the graft section which is in fluid communication with at least one inflatable channel of the graft section, said temporarily longitudinal inflation channel being sealed in locations

between adjacent portions of the at least one inflatable channel after the at least one inflatable channel has been expanded by injection of pressurized fluid and after the graft material of the at least one inflatable channel has been fixed.

5 59. The method of claim 56 further comprising disposing an internal radial support within the graft section prior to expansion of the at least one inflatable channel or cuff.

60. The method of claim 59 wherein the internal radial support comprises a mandrel which is disposed within the graft section prior to placing the graft section into the mold so as to radially support the inside surface of the graft section during injection of the pressurized fluid.

61. The method of claim 56 wherein the graft material of the at least one inflatable channel or cuff is fixed by sintering.

62. The method of claim 56 wherein the graft material of the entire 15 graft section is fixed.

63. The method of claim 56 wherein the graft material is fixed by heating to a temperature of about 335 to about 380 degrees Celsius.

64. The method of claim 56 wherein the graft material comprises ePTFE.

20 65. The method of claim 56 wherein the pressurized fluid is a gas which is injected into the input end of the pressure line at a rate of about 2 to about 30 scfh.

66. The method of claim 56 wherein the pressurized fluid is a gas which is injected into the input end of the pressure line at a rate of about 5 to about 6 scfh.

67. The method of claim 56 wherein the pressurized fluid is a gas 5 which is injected at a rate of about 2 to about 15 scfh.

68. The method of claim 56 wherein the pressurized fluid is a gas which is injected into the pressure line at a pressure of about 5 to about 30 psi.

69. The method of claim 56 wherein the pressurized fluid is a gas which is injected into the pressure line at a pressure of about 35 to about 65 psi.

70. A method of forming at least one inflatable channel or cuff of an endovascular graft or section thereof comprising:

15 a) providing a graft section with at least one inflatable channel or cuff formed between layers of graft material of the graft section in an unexpanded state;

b) providing a mold comprising a main cavity portion having an inside surface contour that corresponds to an outside surface contour of the graft section with the at least one inflatable channel or cuff in an expanded state;

20 c) positioning the graft section in the main cavity portion of the mold with the at least one inflatable channel or cuff of the graft section in an unexpanded state positioned to expand into corresponding channel or cuff cavity portions of the main cavity portion;

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- d) injecting pressurized liquid into the at least one inflatable channel or cuff to expand the at least one inflatable channel or cuff; and
- e) fixing the graft material of the at least one inflatable channel or cuff with the at least one inflatable channel or cuff in an expanded state.

71. The method of claim 70 wherein some expansion of the inflatable channel or cuff is carried out by vapor pressure from boiling of pressurized liquid during fixing of the graft material.

72. An outer constraint means for manufacture of an endovascular graft or section thereof which has at least one inflatable channel or cuff, comprising:

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one or more of outer constraint body means configured to produce an outer constraint means having a main cavity means configured to radially constrain an outside surface contour of a graft section with the at least one inflatable channel or cuff in an expanded state.

73. An outer constraint means for manufacture of an endovascular graft or section thereof which has at least one inflatable channel or cuff, comprising:

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a first outer constraint body means having a main cavity means configured to correspond to an outside surface contour of a graft section with the at least one inflatable channel or cuff in an expanded state; and

a second outer constraint body means configured to mate with the first outer constraint body means and configured to correspond to an outside surface contour of the graft section with the at least one inflatable channel or cuff in an expanded state.

5 74. A pressure line for use in the manufacture of an endovascular graft or section thereof comprising:

an elongate gas containment means having an input end, an output end and means for producing a permeability gradient which increases with distance from the input end along a section of the elongate gas containment means.

10 75. An assembly for manufacture of an endovascular graft or section thereof which has at least one inflatable cuff or channel on a graft section, comprising:

15 a) an interior surface support means configured to support an inside surface of the graft section;

b) the graft section having at least one inflatable cuff or channel disposed about at least a portion of the interior surface support means;

c) a pressure line comprising an elongate gas containment means having an input end, an output end and means for producing a permeability gradient which increases with distance from the input end along a section of the elongate gas containment means;

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d) an outer constraint means at least partially disposed about the graft section, the pressure line and the interior surface support means, comprising a plurality of outer constraint body means configured to mate with at least one of the other outer constraint body means to produce an assembled outer constraint means configured to radially constrain an outside surface contour of the graft section with the at least one inflatable channel or cuff in an expanded state during expansion of the cuff or channel.

76. A method of forming at least one inflatable channel or cuff of an endovascular graft or section thereof comprising the steps of:

a) providing an endovascular graft section with at least one inflatable channel or cuff formed between layers of graft material of the graft section in an unexpanded state;

b) providing an outer constraint means configured to radially constrain an outside surface contour of the graft section with the at least one inflatable channel or cuff in an expanded state during expansion of the cuff or channel;

- c) positioning the graft section within the outer constraint means with the at least one inflatable channel or cuff of the graft section in an unexpanded state positioned to expand into a corresponding channel or cuff cavity of the outer constraint means;

- d) expanding the at least one inflatable channel or cuff with pressurized fluid;

e) fixing the graft material of the at least one inflatable channel or cuff with the at least one inflatable channel or cuff in an expanded state.

77. The method of claim 76 further comprising the step of positioning
5 a pressure line comprising an elongate gas containment means having an input end, an output end and means for producing a permeability gradient which increases with distance from the input end along a section of the elongate gas containment means and passing expansion material into the at least one inflatable channel or cuff through the means for producing a permeability gradient.

78. The method of claim 76 further comprising disposing an interior surface support means configured to support an inside surface of the graft section within the graft section prior to expansion of the at least one inflatable channel or cuff.

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